

REMARKS

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner has indicated consideration of the Supplemental Information Disclosure Statement filed September 17, 2009.

The election of species requirement is made final and claims 50-53, 55-59, 63 and 64 are withdrawn from consideration.

Claims 65 and 69-71 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

Claims 48, 49, 54, 60-62 and 65-71 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement.

Claims 48, 49, 54, 61, 62, 65-69 and 71 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Lilley et al., GB 2 359 746 (hereafter "LILLEY").

Claims 60 and 70 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY in view of Gail B. Mahady, Thai Journal of Phytopharmacy, Vol. 9(1), pp. 50-62 (hereafter "MAHADY").

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested, in view of the following remarks.

Response to Rejection under 35 U.S.C. § 112, Second Paragraph

Claims 65 and 69-71 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite for allegedly failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention because of the recitation of a “pure form” of oil of coriander in claims 65 and 69. The rejection alleges that the Examiner “does not know if ‘pure form’ means that the oil has been purified or if coriander is administered alone”.

Applicants respectfully traverse this rejection. In particular, the meaning of the term “pure form of oil of coriander” is set forth in detail in the instant specification. In this regard see, e.g., page 8, second paragraph of the specification.. Basically, the term “pure form” is used throughout the specification to distinguish this form of oil of coriander from “compositions of oil of coriander”, i.e., compositions which in addition to oil of coriander may comprise solvents and other components such as, e.g., components, stemming from the process of obtaining oil of coriander from its natural sources.

It is submitted that for at least the foregoing reasons, the instant rejection is unwarranted and should be withdrawn, which action is respectfully requested.

Response to Rejection under 35 U.S.C. § 112, First Paragraph

Claims 48, 49, 54, 60-62 and 65-71, i.e., all claims under consideration, are rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the enablement requirement. The rejection asserts that the specification, while being enabling for a method of treating microbe-caused disease of at least one skin condition disclosed in the instant claims, allegedly does not reasonably

provide enablement for preventing a microbe-caused disease. In this regard, the Examiner takes the position “that the term ‘preventing’ is an absolute definition which means to stop from occurring and thus, requires a higher standard for enablement than does ‘treating’, especially since it is notoriously well accepted in the medical art that the vast majority of afflictions/disorders suffered by mankind cannot totally prevented with current therapies (other than certain vaccination regimes) – including preventing such any and all [*sic*] microbe-caused disease (which clearly is not recognized in the medical art as being totally preventable condition)”. Page 9, last paragraph of the instant Office Action.

This rejection is respectfully traversed as well. Initially, it is noted that in the above-cited passage from the instant Office Action the Examiner on the one hand alleges that the term “preventing” is an absolute definition and on the other hand refers uses terms like “totally prevented” and “totally preventable” which indicates that the Examiner acknowledges that “prevention” may be partial (otherwise “totally” in connection with “prevented” or “preventable” would not make sense). For this reason alone, the Examiner’s allegation that the term “preventing” requires a higher standard for enablement than the term “treating” is apparently without merit.

At any rate, the Examiner’s definition of “prevention” is completely different from the definition which should be applied here, i.e., the definition in the medical field, as explained below.

It appears that the Examiner considers “prevention” to be something that is completely different from “treatment”. This is, however, completely erroneous, as is well known to one of ordinary skill in the art. This can also be derived from trivial literature sources (see, for example, http://en.wikipedia.org/wiki/Preventive_medicine and <http://simple.wikipedia.org/wiki/Prophylaxis>)

and from medical textbooks where prevention or prophylaxis of diseases is often named “preventive/prophylactic therapy”.

It is well known (and may be shown by many examples) that the preventive/prophylactic therapy of a disease is effected by administering the same agent (e.g., oil of coriander) by the same route of administration (e.g., oral, topical routes) in the same amounts (as disclosed in the present application and described in working examples) against the (or for a prevention/prophylaxis of an) appearance of the same disease and with the (reasonable) expectation that the (same) disease will not appear.

One (well-known) example is a preventive/prophylactic treatment of embolism which is effected by the same route of administration (intravenous) in the same amounts of the same agent (e.g., heparin) as a treatment of chronic embolism. Another (well known) example for classical antibiotics is the prevention/prophylaxis of germ appearance and starting of a germ infection caused by surgery, where the preventive/prophylactic treatment comprises the administration to the patient of an antibiotic just before or in the course of a surgery by the same route and in the same amount as would be the route/amount for the treatment of the infection after its appearance. Another similar (well known) example (as disclosed in the present application) is the preventive/prophylactic treatment of caries in the oral cavity by an administration, by the same route (oral) and in the same amount (see the present specification) of the same agent (oil of coriander) to the “patient” as in cases of a treatment of dental caries.

Finally, the subject matter specifically recited in claim 60, i.e., the preventive/prophylactic treatment of a patient against the presence of Methicillin-resistant *Staphylococcus aureus* in a

hospital (as described at page 12 of the specification and in the Examples at page 18, paragraph before Table 1) is, basically, a preventive/prophylactic therapy. In particular, the administration of oil of coriander to patients in a hospital by topical administration (onto the nasal mucosa (nasopharyngeal space or oropharyngeal space)) in similar amounts as in the case of a treatment serves the prevention of severe hospitalism diseases and is a typical example for a preventive/prophylactic therapy: patients are prevented from being affected by said bacteria and, in addition, are prevented from developing a resistance (which is the best way of preventive/prophylactic therapy conceivable, i.e., before any disease appears from an uncontrollable propagation of the germs).

In other words, there exists a broad knowledge that preventive/prophylactic treatment and "actual" treatment are effected (i) by the same agent (ii) by the same route of administration (iii) in the same amounts and (iv) against the same disease.

Furthermore, there is guidance in the specification and in the working examples for preventive and therapeutic treatments that allows a person of ordinary skill in the art (e.g., a medical practitioner) to apply the preventive/prophylactic treatment/therapy in the same way as an actual therapy (of an already existing disease).

Moreover, it is well known that such preventive/prophylactic therapy is effected in the same way and actually has the same effect as the actual therapy: the disease will not appear or will appear to a minor extent, compared to a situation where no prophylactic therapy was carried out. There are numerous well-known examples even in the field of treatment of microbe-caused diseases upon which a person of ordinary skill in the art can rely (i.e., even without needing the guidance provided

by the instant specification).

Further, no experimentation (let alone undue experimentation) is necessary for verifying such a preventive/prophylactic therapy treatment. Even the present specification provides guidance in this regard (example: MRSA). Following this guidance will automatically result in the desired preventive/prophylactic therapy; a microbe-caused disease will not appear or will appear to an extent that is much less severe than in cases without any preventive/prophylactic therapy at all.

To sum up, the Examiner's allegations in this regard are not supported by the medical facts: as is well known (particularly for microbe-caused diseases), the measures to be taken for a preventive/prophylactic treatment do not at all differ from the measures that are to be taken for an "actual" (therapeutic) treatment of the (same) disease.

Applicants submit that for at least all of the foregoing reasons and the additional reasons set forth in the response to the previous Office Action (the corresponding remarks are expressly incorporated herein), the rejection under 35 U.S.C. § 112, first paragraph, for alleged failure to comply with the enablement requirement is without merit and should be withdrawn, which action is again respectfully requested.

Response to Rejection under 35 U.S.C. § 103(a) over LILLEY

Claims 48, 49, 54, 61, 62, 65-69 and 71 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY. The Office (again) alleges, *inter alia*, that LILLEY "beneficially teaches the instant claims by disclosing one or more essential oils selected from coriander and others therein for the inhibition of pathogenic bacteria in the oral cavity that define such disorders as

gingivitis, periodontal disease, dental carries and particularly disorders related to or caused by the activity of anaerobic bacteria (gram positive bacteria)". The rejection concedes that LILLEY does not teach the step of administering coriander oil to a mammal but alleges that it would have been obvious to one of ordinary skill in the art to administer oil of coriander to a mammal based on the beneficial teachings provided by LILLEY. The rejection further asserts that "the oral cavity comprise[s] skin, teeth and gum. Therefore the oral cavity read[s] on skin", that the oral cavity includes the skin and that "[t]he oral cavity is made of skin, teeth and bone". Page 6, last paragraph, page 7, third paragraph and paragraph bridging pages 10 and 11 of the instant Office Action.

Applicants respectfully traverse this rejection for all the reasons which are set forth in the response to the previous Office Action. The corresponding remarks are expressly incorporated herein.

It is noted that in response to Applicants' argument that the previously cited passage of LILLEY, i.e., page 3, lines 14-23, conveys the strong impression that the oils disclosed in LILLEY exhibit significant activity only against "species of bacteria which are strongly implicated in periodontal disease and/or malodour production", which is a disincentive rather than a motivation for one of ordinary skill in the art to use a substance such as oil of coriander for the treatment or prevention of a disease which is not "strongly implicated in periodontal disease and/or malodour production" the Examiner alleges, *inter alia*, that "treatment of the oral cavity includes the skin. The oral cavity is made of skin, teeth and bone." Page 10, last paragraph of the instant Office Action.

In this regard, Applicants point out that they are not aware that the oral cavity includes skin, and neither has the Examiner provided any evidence to support this assertion. For this reason alone,

the instant rejection is without merit.

Additionally, it is to be taken into account that LILLEY only discloses the administration of combinations of essential oils to the oral mucosa of patients (although claiming "at least one").

There is no working example supporting the administration of a single essential oil, let alone of oil of coriander. Further, LILLEY is devoid of any teaching or suggestion that the (allegedly beneficial) effect (wherever the essential oil mixture is applied) may be attributed to the presence of oil of coriander. Even further, any expectation of success (as alleged by the Examiner) may result only from an expectation, which expectation requires some kind of an indication that administration of oil of coriander by itself might be beneficial (as well). There is not the slightest suggestion in LILLEY that if oil of coriander were administered in the absence of any other essential oils it would be effective against any microbe-caused diseases. However, all skill of one of ordinary skill in the art would be useless in the absence of a suggestion that oil of coriander by itself might be helpful against/for the treatment and prophylaxis of microbe-caused diseases. In the absence of a corresponding suggestion one of ordinary skill in the art would not even have a reason to conduct experiments with the aim of finding out whether or not oil of coriander is effective in this respect.

In view of the foregoing, it is submitted that the Examiner's allegation that LILLEY renders the present invention obvious is apparently the result of reading the disclosure of the present specification into LILLEY (hindsight). A person fully familiar with LILLEY would not at all conclude that oil of coriander by itself should be helpful against microbe-caused diseases, and LILLEY fails to provide any incentive to try or test whether oil of coriander by itself may have the effect disclosed in the present specification.

Applicants submit that for at least all of the foregoing reasons, LILLEY is unable to render obvious the subject matter of any of the claims of record, wherefore withdrawal of the rejection under 35 U.S.C. § 103(a) over LILLEY is warranted and respectfully requested.

Response to Rejection under 35 U.S.C. § 103(a) over LILLEY in View of MAHADY

Claims 60 and 70 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over LILLEY in view of MAHADY. The rejection concedes that LILLEY fails to teach that the alleged microbe-caused disease disclosed therein is associated with a Methicillin-resistant *Staphylococcus aureus* and/or a multi-resistant pathogen but essentially alleges that MAHADY cures this deficiency of LILLEY, asserting, *inter alia*, that MAHADY “teaches that such pathogens can become multi-resistant to the over use of antibiotics and therefore need an alternative treatment[] as in essential oils that include coriander”. Page 8, last paragraph of the instant Office Action.

Applicants respectfully traverse this rejection as well. In particular, it is not seen why one of ordinary skill in the art would assume that the “species of bacteria which are strongly implicated in periodontal disease and/or malodour production” that LILLEY is concerned with include Methicillin-resistant *Staphylococcus aureus* and/or multi-resistant pathogens, and neither has the Examiner provided any explanation in this regard.

Further, while MAHADY mentions both Methicillin-resistant *Staphylococcus aureus*/multi-resistant pathogens and oil of coriander, the corresponding passages of MAHADY are not linked at all. In particular, Methicillin-resistant *Staphylococcus aureus*/multi-resistant pathogens are mentioned at page 52, left column of MAHADY in a general context:

The development of resistance in some human pathogens, such as methicillin-resistant *Staphylococcus aureus* and multi-drug resistant *Mycobacterium tuberculosis*, is linked to the use of antimicrobials in man and there is no evidence for animal involvement.

Coriander on the other hand, is mentioned in MAHADY only as one of about 100 plant species from Thailand with active antimicrobial activity. Accordingly, MAHADY fails to provide an apparent reason for one of ordinary skill in the art to use of oil of coriander for the therapeutic or prophylactic treatment caused by Methicillin-resistant Staphylococcus aureus/multi-resistant pathogens.

Further, the teachings of LILLEY and MAHADY are completely unrelated, wherefore it is only with hindsight that one can conclude that one of ordinary skill in the art would be motivated to combine these teachings.

In particular, LILLEY explicitly teaches the treatment of diseases selected from dental caries, gingivitis and/or periodontal disease by oral administration of compositions of, *inter alia*, oil of coriander in the oral cavity.

In contrast, MAHADY has nothing at all to do with the treatment of dental caries, gingivitis and/or periodontal disease but tries to answer the question whether medicinal plants are a potential alternative for conventional antibiotics in animal husbandry (see, e.g., title of MAHADY).

Accordingly, apart from the fact that both documents mention oil of coriander, LILLEY and MAHADY have nothing in common. For example, while LILLEY discloses the use of oils such as oil of coriander in the oral cavity, MAHADY contemplates the use of plant-based medicines for animal borne diseases and as feed additives and growth promoters for animals (page 61, bottom of left column and top of right column of page 61 of MAHADY).

Applicants submit that for at least all of the foregoing reasons, LILLEY in view of MAHADY fails to teach or suggest that oil of coriander is effective for treating diseases caused by *Staphylococcus aureus* and/or multi-resistant pathogens, even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to combine the teachings of LILLEY and MAHADY. In view thereof, it is apparent that the instant rejection under 35 U.S.C. § 103(a) over these documents is without merit as well, wherefore withdrawal thereof is respectfully requested.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, wherefore an early issuance of the Notices of Allowance and Allowability is again respectfully solicited. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,
Matthias AUGUSTIN et al.

/Heribert F. Muensterer/

Heribert F. Muensterer
Reg. No. 50,417

January 28, 2011
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191